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From the
INTERNATIONAL PRELIMINARY E[X]INING AUTHORITY

PCT 10/019100
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COPY

WRITTEN OPINION
(PCT Rule 66)

Woodcock Washburn Kurtz Mackiewicz & Norris LLP

Date of Mailing *(day/month/year)*	10 AUG 2000
Applicant's or agent's file reference LDS-0527	REPLY DUE within ONE months from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US99/14351	24 JUNE 1999	26 JUNE 1998

International Patent Classification (IPC) or both national classification and IPC
IPC(7): A61K 9/27, 31/56 and US Cl.: 424/450; 514/179, 180

Applicant
LDS TECHNOLOGIES, INC.

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I [X] Basis of the opinion
- II [ ] Priority
- III [ ] Non-establishment of opinion with regard to novelty, inventive step or industrial applicability
- IV [ ] Lack of unity of invention
- V [X] Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI [ ] Certain documents cited
- VII [ ] Certain defects in the international application
- VIII [X] Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension., see Rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 *bis*.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 26 OCTOBER 2000.

Name and mailing address of the IPEA/US	Authorized officer
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	F.T. MOEZIE
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0193

Form PCT/IPEA/408 (cover sheet) (July 1998)*

WRITTEN OPINION

Intern[illegible]nal application No.

PC[illegible]99/14351

I. Basis of the opinion

1. With regard to the elements of the international application:*

[ ] the international application as originally filed

[X] the description:

pages 1-24, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of _____

[X] the claims:

pages NONE, as originally filed

pages NONE, as amended (together with any statement) under Article 19

pages 25-28/2, filed with the demand

pages NONE, filed with the letter of _____

[X] the drawings:

pages NONE, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of _____

[X] the sequence listing part of the description:

pages NONE, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

[ ] contained in the international application in printed form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the writen sequence listing has been furnished.

4. [X] The amendments have resulted in the cancellation of:

[X] the description, pages NONE

[X] the claims, Nos. 2-4

[X] the drawings, sheets/~~fig~~ NONE

5. [ ] This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".*

WRITTEN OPINION

Intern al application No.
PCT/US99/14351

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	1 and 5-33	YES
	Claims	none	NO
Inventive Step (IS)	Claims	none	YES
	Claims	1 and 5-33	NO
Industrial Applicability (IA)	Claims	1 and 5-33	YES
	Claims	NONE	NO

2. citations and explanations

Claims 1 and 5-33 lack an inventive step under PCT Article 33(3) as being obvious over Benjamin et al. (US Patent no. 4,782,047) in view of Ly et al. (abstract).

Benjamin et al., teach the use of anti-inflammatory steroids aqueous compositions for nasal administration comprising a surfactant and the conventional additives and carriers. See the entire document, especially the claims. However, the primary reference does not teach the use of a high-HLB surfactant component in the composition. Ly et al., abstract discloses that tocopherol ester-linked polyethylene glycol succinate 1000 (TPGS) is known to have a high-HLB value and "have potential as enhancers of the aqueous solubility of poorly water soluble drugs". One of ordinary skill in the art at the time the invention was made would have been motivated to use a high-HLB surfactant such as taught by the secondary reference in the compositions of the primary reference for further enhancing the aqueous solubility of the steroids and the added benefits of using Vitamin E derivative in the therapeutic composition. To vary the proportions of the ingredients in the compositions is within the skill of an ordinary art skilled.

Claims 1 and 5-33 meet the criteria set out in PCT Article 33(2) and (4), because the prior art does not teach the claims as presented. Moreover, the claims have industrial applicability in the field of medicine.

---------- NEW CITATIONS ----------
NONE

Intern. ...nal application No.
PC... 99/14351

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1 and 5-33 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claims are indefinite for the following reason(s): The term "high" is a relative term and render the claims indefinite as to the claims metes and bounds.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.